

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
24 December 2003 (24.12.2003)

PCT

(10) International Publication Number
WO 03/105674 A2

- (51) International Patent Classification: A61B
(21) International Application Number: PCT/US03/19204
(22) International Filing Date: 17 June 2003 (17.06.2003)
(25) Filing Language: English
(26) Publication Language: English
(30) Priority Data: 60/390,024 18 June 2002 (18.06.2002) US
(71) Applicant (for all designated States except US): TYCO HEALTHCARE GROUP, LP [US/US]; 150 Glover Avenue, Norwalk, CT 06856 (US).
(72) Inventor; and
(75) Inventor/Applicant (for US only): BILSBURY, Andrew, J. [US/US]; 164 Euclid Avenue, Fairfield, CT 06432 (US).
(74) Agents: PERRY, Kimberly, V. et al.; Tyco Healthcare Group, LP, 150 Glover Avenue, Norwalk, CT 06850 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

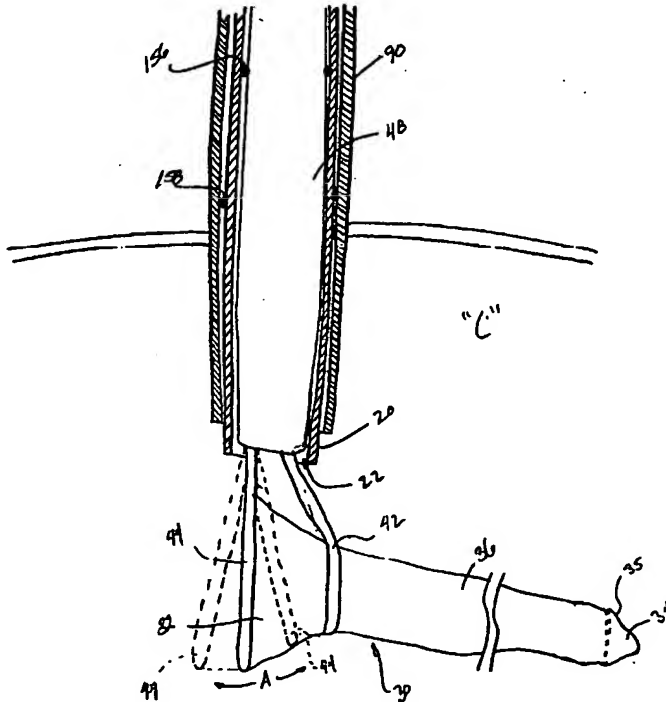
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: TISSUE REMOVAL DEVICE



(57) Abstract: In a tissue removal device for receiving and removing body tissue from an interior portion of a body in a minimally invasive surgical procedure, the tissue removal device including a tubular body having a distal end, a proximal end and defining a lumen therethrough, a bag support structure configured and dimensioned to be receivable within the lumen of the tubular body, wherein the bag support structure has a first configuration for positioning within the lumen of the tubular body and a second configuration for opening a bag operatively coupled thereto, and a bag operatively coupled to the bag support structure, the bag including a first end portion defining an open end.

WO 03/105674 A2

WO 03/105674 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PATENT APPLICATION
Attorney Docket: 2795PCT (203-3173PCT)

TISSUE REMOVAL DEVICE

3

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of and priority to U.S. Provisional Patent Application Serial No. 60/390,024 filed June 18, 2002, the entire contents of which are incorporated herein by reference.

10

BACKGROUND

1. **Technical Field**

The present disclosure relates to tissue removal devices and, more particularly to tissue removal devices for receiving, retaining and/or removing resected matter from a surgical site.

15

2. **Background of Related Art**

Laparoscopic and endoscopic surgical procedures are minimally invasive procedures in which operations are carried out within the body by means of elongated instruments inserted through small entrance openings in the body. The initial opening in the body tissue, to allow passage of the endoscopic or laparoscopic instruments to the interior of the body, may be a natural passageway of the body or may be created by a tissue piercing instrument such as a trocar, a scalpel or a needle.

20

Endoscopic surgery is popular and commonplace for certain surgical procedures, such as gall bladder removal, ovariectomies and appendectomies. In such procedures, diseased, malignant, necrotic or inflamed tissue and/or organs are excised and removed from the patient. In many endoscopic procedures that involve removal of an organ or tissue such as a gall bladder, appendix, colon, spleen, ovary, lymph node, lung, etc., there is a need for a retrieval bag that can carry and/or contain the organ or portion thereof during its removal from the body cavity in order to reduce the potential for contamination of surrounding tissue and/or organs in the body cavity.

25

30

Various apparatus have been devised for introducing, opening, positioning and closing surgical pouches and for removing the pouches and enclosed matter from the surgical site. For example, U.S. Pat. No. 5,037,379 to Clayman et al., the entire contents

of which are incorporated herein by reference, discloses a surgical tissue bag. The bag includes a drawstring. In a disclosed method of use, the bag is placed within the body cavity, the body tissue or organ is placed within the bag, the opening of the bag is pulled through the incision in the skin leaving the distal end of the bag containing the tissue or organ within the body cavity, a morcellator is then inserted into the bag, and then the tissue or organ is debulked and suctioned out of the bag.

In U.S. Pat. No. 5,074,867 to Wilk, the entire contents of which are incorporated herein by reference, there is disclosed a membrane having filaments attached to its corners. The membrane is placed within a body cavity with the filaments extending through a cannula to the outside of the body. If the organ and/or tissue is sufficiently deformable, the organ and/or tissue to be removed is placed within the membrane and the filaments are pulled to close the membrane around the organ and/or tissue. The membrane is then removed from the surgical site. If, on the other hand, the organ and/or tissue is not sufficiently deformable, e.g. because of the presence of gall stones, forceps or other instruments are used to crush the stones or tissue prior to withdrawal.

In U.S. Pat. Nos. 5,465,731 to Bell et al. and 5,647,372 to Tovey et al., the entire contents of which are incorporated herein by reference, there is disclosed a specimen retrieval pouch supported by a loop of flexible material. The pouch has a noose retained proximate its open end and is perforated proximate its attachment to the support loop. After the pouch receives its intended contents at the surgical site, it is cinched closed by pulling upon a suture leading to the noose. Cinching the pouch closed aids the separation of the pouch from the support loop via tearing along the perforation line. Once the pouch has been torn from the expanded loop pouch support, the support may be retracted and the instrument withdrawn.

Although retrieval bags such as those described above are known, there remains a need for improved specimen retrieval pouches to facilitate tissue removal in minimally invasive surgical procedures. There remains a need for specimen retrieval pouches that minimize the wound at the exit site for removing the pouch after the pouch has received tissue.

30

SUMMARY

The present disclosure relates to tissue removal devices for receiving, retaining and/or removing resected matter (e.g., body tissue and/or body organs) from a surgical site.

According to one aspect of the present disclosure, a tissue removal device includes a tubular body having a distal end, a proximal end and defining a lumen at least partially therethrough, and a bag support structure configured and dimensioned to be receivable within the lumen of the tubular body. The bag support structure has a first configuration
5 for positioning within the lumen of the tubular body and a second configuration for opening a bag operatively coupled thereto. The device further includes a bag operatively coupled to the bag support structure, the bag including a first end portion defining an open end, a mid-portion, and a second end portion opposite the first end portion. The bag support structure includes a first member disposed between the first end portion and the
10 second end portion for at least partially closing the bag. The first member may be used to manipulate tissue while disposing the tissue in the bag.

In certain preferred embodiments, the bag support structure includes a shaft extending through the lumen of the tubular body, the shaft including a distal end and a proximal end. The first member is desirably slidably received in the shaft. The bag
15 support structure preferably includes a second member disposed at the first end portion of the bag. The first member may be used to engage tissue and to position tissue while the second member is used to close the open end of the bag. The device may be used in various procedures and may be used to position a first length of tissue within the bag, closing the first member, and the positioning a second length of tissue in the bag and
20 closing the second member.

It is envisioned that the first member includes a first hoop translatably received in the shaft and the second member includes a second hoop translatably received in the shaft. The first hoop is desirably spaced from the second hoop in the longitudinal direction of the bag.

25 Each of the first and second members desirably has a first position in which the bag is substantially closed and a second position in which the bag is substantially open. Each of the first and second members is desirably made of a flexible member extending through at least one aperture formed in the distal end of the shaft.

It is envisioned that displacement of the first and second members in a distal
30 direction urges the respective one of the first and second members to the second position. It is further envisioned that displacement of the first and second members, in a proximal direction, urges the respective one of the first and second members to the first position.

In certain embodiments, each of the first and second members has a first end secured to the distal end of the shaft and a second end extending through the distal end of

the shaft. Accordingly, displacement of the second end of each of the first and second members, in a proximal and distal direction, urges the first and second members between the first and second position.

In certain embodiments, the first member of the bag support structure includes a
5 ring, and a rod operatively connected to the ring. The bag support structure further includes a hoop disposed at the first end portion of the bag. The frame is spaced a transverse distance from the hoop.

The first member is desirably made of a deformable material. Preferably, the first
10 member is biased to a second position in which the bag is substantially open. The deformable material can be any one of stainless steel, titanium, a composite material, a shape memory alloy and plastic.

The bag desirably has a generally elongate shape. In certain embodiments, the bag
has a mid-portion with a generally elongate shape. The mid-portion of the bag desirably has a first diameter and the first end portion of the bag desirably has a second diameter
15 which is greater than the first diameter of the mid-portion.

The tissue removal device further preferably includes a removable sheath for encasing the bag and at least a portion of the bag support structure therein.

In certain embodiments, the tissue removal device further includes a plurality of
20 ribs extending longitudinally along a length of the bag.

The tissue removal device may further include a grasper operatively coupled to a
distal end of the bag support structure.

In one embodiment, the first member includes a first hoop operatively connected to
the first end portion of the bag, and wherein a second member includes a second hoop
operatively connected to the bag at a location spaced a distance from the first end portion.
25 Each of the first and second hoops has a first configuration in which the bag is
substantially closed and a second configuration in which the bag is substantially open.

Each of the first and second hoops may be made of a wire extending through at
least one aperture formed in the distal end of the shaft. Accordingly, displacement of the
wire of each of the first and second hoops, in a distal direction, urges the respective one of
30 the first and second hoops to the second configuration. Moreover, displacement of the
wire of each of the first and second hoops, in a proximal direction, urges the respective
one of the first and second hoops to the first configuration.

In another embodiment, the first member includes a ring operatively connected to a
distal end of a rod. The ring is also operatively connected to the first end portion of the

bag, and wherein the hoop is operatively connected to the bag at a location spaced a distance from the first end portion of the bag.

The ring is desirably resilient. The ring has a first configuration in which the ring is biased for receipt in the lumen of the tubular body and a second configuration in which
5 the ring is unbiased and has a diameter larger than the diameter of the lumen of the tubular body.

It is envisioned that a mid-portion of the bag has a first diameter and the first end portion of the bag has a second diameter which is greater than the first diameter of the mid-portion.

10 The tissue removal device can further include a removable sheath for encasing the bag and the distal end of the bag support structure therein.

The tissue removal device can further include a plurality of ribs extending longitudinally along a length of the bag.

The present disclosure is also related to a method of removing body tissue from an
15 interior portion of a body in a minimally invasive surgical procedure. The method includes the step of introducing a tissue removal device into the body, wherein the tissue removal device includes a bag support structure and a bag operatively connected to the bag support structure, the bag support structure including a first member disposed between a first end portion and a second end portion of the bag for at least partially closing the bag.

20 The method further includes the steps of deploying the bag from a first configuration to a second configuration in which the bag is substantially open, introducing body tissue into the bag, and manipulating the first member so as to at least partially close the bag.

In certain embodiments, the step of manipulating the first member includes
25 engaging the body tissue. The bag support structure preferably includes a second member at the first end portion of the bag, and the method preferably includes manipulating the second member to at least partially close the bag. In certain preferred embodiments, the device is used to position a first length of tissue in the bag, close the first member and then position a second length of tissue in the bag and close the second member.

30 These and other advantages and features of the present apparatus disclosed herein, will become apparent through reference to the following description of embodiments, the accompanying drawings and the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

By way of example only, preferred embodiments of the present disclosure will be described herein with reference to the accompanying drawings, in which:

FIG. 1 is a perspective view of a distal end of a tissue removal device in accordance with one embodiment of the present disclosure, shown in a second or opened deployed condition;

FIG. 2A is an enlarged perspective view of the tissue removal device of FIG. 1;

FIG. 2B is an enlarged perspective view of a distal end of a tissue removal device according to another embodiment of the present disclosure;

FIG. 2C is an enlarged perspective view of a distal end of a tissue removal device according to yet another embodiment of the present disclosure, wherein one end of the first and/or second hoop is movable;

FIG. 3 is an enlarged perspective view of the tissue removal device of FIGS. 1 and 2A shown in a first or closed/folded condition;

FIG. 4 is a cross-sectional side elevational view of the tissue removal device of FIGS. 1, 2A and 3 as it is inserted into a body cavity through a cannula;

FIG. 5 is a side elevational view of the tissue removal device of FIGS. 1, 2A, 3 and 4, in a second or deployed condition, in the body cavity;

FIG. 6 is a schematic side elevational view, partially broken away, of the tissue removal device of FIGS. 1, 2A and 3-5, at a stage in a method of the present disclosure, illustrating positioning of body tissue and/or organs into the bag;

FIG. 7 is a schematic cross-sectional side elevational view of the tissue removal device of FIGS. 1, 2A and 3-6, shown at a later stage of the method of the present disclosure, illustrating the removed body tissue and/or organ contained in the bag;

FIG. 8 is a cross-sectional side elevational view of the tissue removal device of FIGS. 1, 2A and 3-7, shown in a later stage of the method of the present disclosure, illustrating withdrawal of the tissue removal device, containing body tissue and/or organs, from the body cavity; and

FIG. 9 is a perspective view of a tissue removal device in accordance with an alternative embodiment of the present disclosure.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of a presently disclosed tissue removal device will now be described in detail with reference to the drawing figures wherein like reference numerals

identify similar or identical elements. In the drawings and in the description which follows, the term "proximal", as is traditional will refer to the end of the surgical device or instrument of the present disclosure which is closest to the operator, while the term "distal" will refer to the end of the device or instrument which is furthest from the operator.

One embodiment of a tissue removal device, in accordance with the present disclosure, is shown in FIGS. 1, 2A and 3-8. Tissue removal device 10 includes an endoscopic shaft or tubular body 20 having a lumen 22 extending therethrough and defining a longitudinal axis "X". Tissue removal device 10 further includes a bag support structure 40 having a bag 30 operatively connected thereto. Desirably, bag support structure 40 is receivable in lumen 22 of tubular body 20. Bag support structure 40 may comprise any openable structure. Bag 30 may be connected to bag support structure 40 by a variety of known means such as the upper end of bag 30 being configured to receive bag support structure 40. Bag 30 comprises a flexible film or sheet and may comprise a substantially transparent polymeric material. Polyurethane, latex and any other bio-compatible material may be used. Bag 30 has dimensions suitable for entrapping and/or removing tissue.

Bag 30 has a first end portion 32 defining an opening 31. Bag 30 also has a second end portion 34 defining a closed end 35 opposite the first end portion 32 and a mid-portion 36 between the first end portion 32 and second end portion 34. It is contemplated that tubular member 20 can be a rigid or a flexible member. Tubular body 20 has an outside diameter configured for passage through a cannula 90 (see FIG. 4).

As best seen in FIGS. 1, 2A and 3, bag support structure 40 includes an elongate shaft 48 having a distal end 48a and a proximal end 48b. It is envisioned that support structure 40 is configured and adapted to be directed or manipulated by a surgeon using a control portion 60 (see FIG. 6). Bag support structure 40 further includes a first member 42 operatively associated with distal end 48a of shaft 48 and a second member 44 operatively associated with distal end 48a of shaft 48 and spaced a longitudinal distance along a transverse axis "Y" from first member 42. Desirably, first member 42 is translatably received in and/or exits distal end 48a of shaft 48 through a pair of apertures 47a, 47b formed therein, and forms a hoop. In addition, second member 44 is desirably translatably received in and/or exits distal end 48a through a pair of apertures 46a, 46b formed in distal end 48a and forms a hoop. While a pair of apertures 46a, 46b and 47a, 47b are provided for each of first member 42 and second member 44, it is envisioned that

each member 42, 44 can exit a respective aperture formed in distal end 48a of shaft 48 or both hoops 42, 44 exit a common aperture formed in distal end 48a of shaft 48.

First member 42 is preferably formed of a relatively flexible wire or band which exits aperture 47a and enters aperture 47b of shaft 48. Desirably, the wire of first member 42 extends proximally through shaft 48 and enables the surgeon to adjust and control the dimensions of first member 42, preferably from control portion 60. First member 42 is operatively connected between the junction between first end portion 32 and mid-portion 36 of bag 30. An adjustable first member 42 has the advantage that the diametral size of the hoop can be reduced while tissue removal device 10 is being inserted through cannula 90 and can thereafter be expanded remotely after insertion into the body cavity. Further, as will be discussed in greater detail below, an adjustable first member 42 permits closure of bag 30 after the resected body tissue has been placed therein and for the withdrawal of tissue removal device 10 back through cannula 90.

Second member 44 is also preferably formed by a relatively flexible wire or band and, as will be described in greater detail below, is preferably operatively connected to first end portion 33 of bag 30. Desirably, the wire of second member 44 extends proximally through shaft 48 and enables the surgeon to adjust and control the dimension of second member 44 from control portion 60, thereby selectively opening and closing interior 33 of bag 30. Second member 44 can also be reduced in diameter for insertion through a cannula and for closing the bag. As will be discussed in greater detail below, first member 42 may be used to assist in the loading of resected body tissue portions into bag 30 by temporarily holding at least a portion of the resected body tissue while the remaining portion of the resected body tissue is positioned through opening 31 during the loading sequence of bag 30. Preferably, first member 42 is configured and adapted to be independently adjusted with respect to second member 44, however, it is envisioned that first member 42 can be adjusted simultaneously with second member 44.

First and second members 42, 44 are preferably fabricated from a wire or band of material capable of providing structural support for as well as being capable of being connected to bag 30. First and second members 42, 44 are preferably made of a suitable medical grade metal, composite or plastic material having the required structural integrity to provide support and flexibility for deforming when being inserted through the cannula into the body cavity and the required rigidity to enable enlargement of opening 31 of bag 30 after deployment of tissue removal device 10. First and second members 42, 44 are desirably comprised of any flexible and/or resilient material and are preferably biased to

an open position. Preferably, first and second members 42, 44 are maintained within the tubular body 20, in a closed position. In the closed position, second member 44 closes opening 31. First member 42 closes around bag 30, between first end portion 32 and mid portion 36. It is contemplated that first and second members 42, 44 can be formed from
5 shape memory alloys, assuming predefined shapes, such as, for example, quadrangular, circular or other geometric two-dimensional or three-dimensional configurations.

Turning now to FIG. 2B, an alternate embodiment of a bag support structure is shown generally as 140. Bag support structure 140 is similar to bag support structure 40 and will only be discussed in detail to the extent necessary to identify differences in
10 construction and operation.

As seen in FIG. 2B, first member 42 has been replaced with a frame 142 having an elongate rod 144 having a distal end 144a and a ring 146 operatively connected to distal end 144a of rod 144. Desirably, rod 144 is translatablely received in shaft 48 such that a distal end of rod 144 exits distal end 48a of shaft 48 through an aperture 148 formed
15 therein and a proximal end of rod 144 extends proximally through shaft 48 and enables the surgeon to position and control ring 146. Ring 146 is operatively connected to first end portion 32 of bag 30.

Ring 146 is preferably fabricated from a wire or band of other material capable of supporting bag 30. Ring 146 is made of a suitable medical grade metal, composite or
20 plastic material having the required structural integrity to provide support, as well as flexibility for deforming for being positioned in lumen 22 of tubular body 20. Ring 146 should have sufficient rigidity to enlarge and open opening 31 of bag 30 after deployment of tissue removal device 10. It is contemplated that ring 146 can be formed from shape memory alloys, assuming predefined shapes, such as, for example, quadrangular, circular
25 or other geometric two-dimensional or three-dimensional configurations.

Turning now to FIG. 2C, an alternate embodiment of a bag support structure is shown generally as 240. Bag support structure 240 is similar to bag support structure 40 and will only be discussed in detail to the extent necessary to identify differences in
construction and operation.

As seen in FIG. 2C, first member 42 has a first end 42a fixedly secured to distal end 48a of shaft 48 and a second end 42b which is translatablely received in and/or extends through an aperture 246b formed therein. In addition, second member 44 has a first end 44a fixedly secured to distal end 48a of shaft 48 and a second end 44b which is
30 translatablely received in and/or extends through an aperture 247b formed therein.

Desirably, second ends 42b, 44b of first and second members 42, 44 extend through shaft 48 to a proximal end thereof. In this manner, the surgeon can move second ends 42b, 44b in a proximal or distal direction to enlarge and/or constrict the size of first and second members 42, 44 as needed.

5 Bag 30 and bag support structure 40 have a first, pre-deployed condition, as shown in FIG. 3, and a second, deployed condition as shown in FIGS. 1 and 5. As seen in FIGS. 1 and 5, bag 30 defines an interior 33 extending from the opening 31 to the closed end 35 when in the deployed condition. In accordance with the present embodiment, first end portion 32 preferably has a conical or tapered shape that transitions from opening 31 to mid-portion 36. Accordingly, opening 31 has a larger diameter than interior 33, in mid-portion 36, wherein first end portion 32 is a chute-like opening which facilitates the introduction of portions of body tissue and/or organs through opening 31 of first end portion 32 and mid-portion 36. It is contemplated that while in the deployed condition, first end portion 32 and mid-portion 36 are centrally aligned along an axis "Y". Although
10 bag 30 is shown with a closed end 35, a tapered first end portion 32 and an enlarged mid-portion 36, bag 30 may comprise other shapes.

 Bag 30 is configured and adapted for the positioning, retention and withdrawal of portions of body tissue and/or organs, such as, for example, a resected portion of a colon, through cannula 90. In general, the dimensions of a tissue removal bag, carrying tissue for removal through a cannula, is limited by the inside diameter of the cannula. As such,
20 quantities of resected portions of body tissue and/or organs which cause the bag to expand to a dimension which is greater than the diameter of the cannula can not be placed within the bag and can not be removed in a single step. Accordingly, it is contemplated that bag 30 be provided with an extended or elongated mid-portion 36 thus allowing for a greater quantity of resected portions of body tissue and/or organs to be contained within bag 30 and distributed along the longitudinal axis "Y" of bag 30, so that a greater quantity of
25 tissue can be removed from the body cavity in a single step. In other words, the tissue and/or organ can be positioned for removal from the body via a relatively smaller exit wound. Preferably, bag 30 has suitable strength and flexibility in order to be withdrawn through the cannula while still retaining its load of resected tissue material. It is further
30 contemplated that bag 30 can be configured with folds, pressure vessel releases or secondary passageways to ensure that air will not be trapped in lumen 33 of bag 30 as body tissue and/or organs are placed therein.

Preferably, bag 30 is made from a flexible film or sheet formed from a substantially transparent polymeric material. In one preferred embodiment, bag 30 is fabricated from polyurethane having a thickness of about 0.001 to about 0.005 inches. It is envisioned that other appropriate biocompatible materials capable of forming a flexible membrane, such as, for example, latex, having other appropriate thicknesses, may be used as well. In certain preferred embodiments, the material of bag 30 is transparent to permit viewing of its contents. In addition, the material should be selected such that bag 30 is impervious to penetration, seepage or leaking of cells or any material therethrough.

Desirably, device 10 has a control portion 60 for relative manipulation of shaft 48, tubular body 20 and hoops 42, 44.

In the pre-deployed condition, as seen in FIG. 3, it is envisioned that bag 30 and support structure 40 may be at least partially encapsulated by a sheath 25 which is configured and adapted to be removed after passage of bag 30 and support structure 40 through lumen 22 of tubular body 20. In certain embodiments, bag 30 is folded or rolled into a shape minimizing its dimensions prior to sheath 25 being placed therearound. For example, bag 30 has at least one transverse fold, as disclosed in certain embodiments of International Application No. PCT/US03/09133, filed March 21, 2003, the disclosure of which is hereby incorporated by reference herein. It is contemplated that bag 30 and support structure 40 can be minimized with the aid of mechanical or pneumatic (e.g., vacuum) means for reducing the volume of bag 30 and the dimensions of support structure 40. After bag 30 and support structure 40 have been minimized, sheath 25 is slipped over bag 30 and supporting structure 40 such that bag 30 and supporting structure 40 retain their minimized configurations. In this manner, as seen in FIG. 3, bag 30 and supporting structure 40 are sized and dimensioned to be received in lumen 22 of tubular body 20. Preferably, device 10 is provided with the collapsed and minimized bag 30 and bag support structure 40 housed in the lumen 22, prior to use.

In use, first member 42 can be rotated about longitudinal axis "X" by rotating elongate shaft 48 about the "X" axis. It is desirable that first member 42 is bendable, in the directions indicated by double-headed arrow "A" in FIG. 5, relative to shaft 48. The bendability of second member 44 enables positioning and orientation of second member 44 in plane X-Y. Bag support structure 40 is further positioned by rotating shaft 48 so that second member 44 is positioned and oriented in planes transverse to the X-Y plane. The bendable second member 44 advantageously allows positioning of first member 42 for greater control of supporting structure 40 to capture resected body tissue and/or organs

into bag 30. Shaft 48 is made of suitable medical grade metals, composites or plastics having the required structural integrity and flexibility for positioning and withdrawing of bag 30 through cannula 90.

Referring now to FIGS. 4-8, the use of tissue removal device 10 will be described.

5 Bag supporting structure 40 and bag 30 are disposed in the first pre-deployed condition. Tissue removal device 10 is introduced into body cavity "C" via tubular body 20 received in the cannula 90. After tissue removal device 10 has been introduced into body cavity "C", sheath 25 is removed to thereby expose and/or release bag 30 and bag support structure 40.

10 With bag 30 and bag support structure 40 released, tissue removal device 10 can be manipulated from the first pre-deployed condition to the second deployed condition. Shaft 48 is extended so that first and second members 42, 44 are exposed. As first and second members 42, 44 are biased to the open position, bag 30 is opened upon release from tubular body 20. Bag 30 unrolls and extends away from first and second members 42, 44.

15 In the second condition, tissue retrieval device 10 is ready to receive portions of resected body tissue and/or organs therein. While in the second condition, first member 42 can be expanded and/or contracted by moving the wires or bands of first member 42 in a distal and proximal direction to thereby open and/or close opening 31 of bag 30. In addition, second member 44 can be expanded and/or contracted by moving the wires or bands of
20 second member 44 in a distal and a proximal direction to thereby open and/or close mid-portion 36 of bag 30. First and second members 42, 44 may be further moved in the distal and proximal directions to position bag 30 and ease the capture of tissue within bag 30. First and second members 42, 44 may be manipulated individually or together.

An illustrative example of the placement of resected portions of body tissue and/or
25 organs into bag 30 of tissue removal device will now be described with reference to FIGS. 6 and 7. Once resected body tissue, such as, but not limited to a resected colon 80, is introduced into bag 30 and into mid-portion 36, first member 42 is retracted to hold a portion of resected colon 80, while the remaining portion of resected colon 80 is positioned through opening 31 of bag 30. In addition, with a portion of resected colon 80
30 being held in place against movement by cinched first member 42, the remaining portion 81 of resected colon 80 can be properly oriented and held in place during its removal from the surrounding body. With the remaining portion 81 of resected colon 80 removed from the surrounding body, the remaining portion 81 of resected colon 80 is placed in first end portion 32 of bag 30. First member 42 is then expanded so that the remaining portion 81

of resected colon 80, retained in first end portion 32, can be fully received into mid-portion 36. For larger pieces of resected body tissue, this process can be repeated as many times as necessary until the entire resected colon 80 is retained in mid-portion 36 of bag 30. In order to maximize the use of bag 30, resected colon 80 is advanced through interior 33 until it is positioned near second end portion 34 of bag 30.

It is envisioned that this process can also be assisted with the aid of a grasper 70 (see FIG. 9) operatively coupled to a distal end of tubular body 20, or with a separate grasper configured and adapted to operate in cooperation with tissue removal device 10, or with a conventional grasper.

As seen in FIG. 8, when bag 30 is fully loaded or when all of the desired portions of resected body tissue and/or organs to be removed have been loaded into bag 30, first and second members 42, 44 are withdrawn, either individually or together, from control portion 60 to reduce the operable diameters of members 42 and 44. In other words, first member 42 is cinched in order to prevent the escape of portions of resected colon 80 from within bag 30 and to reduce the diameter of first member 42 in order to enable the withdrawal of bag support structure 40 through tubular body 20. Meanwhile second member 44 is cinched to reduce its diameter in order to enable its withdrawal through tubular body 20 as well as to provide a second closure to bag 30 to ensure that the portions of resected colon 80 do not inadvertently or accidentally escape from bag 30.

In use, sheath 25 may be removed after deploying bag 30 and support structure 40 from tubular body 20.

While a first member 42 and a second member 44 have been disclosed, it is envisioned that any number of members can be provided along the longitudinal length of bag 30. Accordingly, bag 30 can be of any three dimensional configuration, including but not limited to cylindrical, spherical, rectangular, cubical, etc. Each of these configurations can be achieved by placing an expandable member at a pre-selected location along the length of bag 30 and then expanding the member according to the desired shape and configuration required. While many shapes are possible, it is preferable that bag 30 have a substantially elongated cylindrical configuration (e.g., in the form of a sausage bag) in order for bag 30 to be most easily withdrawn through tubular body 20 after bag 30 has been filled.

It is further contemplated that the elongate shaft of the tissue removal device be provided with circumferential slots (not shown) formed along the inner surface thereof for receiving O-ring type seals 156 (see FIGS. 4, 5 and 8). O-rings 156 help to maintain a

gaseous seal while permitting sliding movement of elongate shaft 48 through tubular body 20. Similarly, it is envisioned that tubular body 20 be provided with circumferential slots (not shown) formed along the outer surface thereof for receiving additional O-ring type seals 158. O-rings 158 help to maintain a gaseous seal while permitting sliding movement of tubular body 20 through cannula 90.

As seen in FIGS. 2A, 2B, 2C and 3, the elongate shaft 48 is longitudinally divided along a plane "P" to define a first-half shaft portion 49a and a second-half shaft portion 49b. It is envisioned that first-half shaft portion 49a and second-half shaft portion 49b can be configured and adapted to be separated from one another and interchanged and/or replaced with other half sections which provide the surgeon with an operative end as desired. For example, half sections including support structures 40 (FIG. 2A), 140 (FIG. 2B) and/or 240 (FIG. 2C) as well as graspers 70 can be combined with and/or interchanged with one another to perform certain functions desired by the surgeon during the surgical procedure. In other embodiments, the shaft 48 comprises a single unitary shaft.

Referring now to FIG. 9, an alternative embodiment of a tissue removal device, in accordance with the present disclosure, is shown generally as 300. Tissue removal device 300 is similar to tissue removal device 10 and will only be discussed in detail to the extent necessary to identify differences in construction and operation

As seen in FIG. 9, bag 330 of tissue removal device 300 includes a plurality of ribs 350 operatively associated (e.g., woven into, glued onto, etc.) around the circumference of mid-portion 336 of bag 330. Desirably, when bag support structure 340 is in the second condition, as seen in FIG. 9, ribs 350 extend substantially in the direction of axis "Y". Bag 330 can further include a plurality of ribs 352 operatively associated around the circumference of first end portion 32 of bag 30. Desirably, ribs 352 extend substantially between opening 331 and mid-portion 336 of bags 330.

Ribs 350 and 352 provide bag 330 with shape and definition when tissue removal device 300 is in the second, deployed condition. In other words, when in the second deployed condition, ribs 350, 352 assist bag 330 in extending/expanding to its full dimensions.

Ribs 350, 352 are fabricated from a wire or band and is configured and adapted to provide structural support for bag 330. The wire stock is made of a suitable medical grade metal, composite or plastic material having the required structural integrity to provide support and flexibility for deforming when being inserted through the cannula into the

body cavity as well as the required rigidity to enable remote enlargement of bag 330 to its full dimensions after deployment of tissue removal device 300.

5 It is envisioned that a fiber optic viewing system (not shown) is employed in conjunction with the supporting structure. It is contemplated that the fiber optic viewing system be operatively coupled to the control portion 360 such that the fiber optic viewing system moves together with a movement of the first member 42 and/or second member 44.

10 Although illustrative embodiments of the present disclosure have been described herein, it is understood that the disclosure is not limited to those precise embodiments, and that various other changes and modifications may be affected therein by one skilled in the art without departing from the scope or spirit of the disclosure. For example, the sheath for containing the bag and support structure may be omitted or may be provided in the form of a housing or container. The bag may be advanced from the lumen of the tubular body prior to removing the sheath, and the bag may be deployed upon removal of the sheath or release from the lumen, or both. In certain embodiments, the tubular body may be omitted and the hoops may be deployed from openings in the shaft. The hoops may be deployed upon removal of the sheath, removal from the lumen of the tubular body or an opening of the shaft, or may be manipulable at their proximal ends for opening and closing the hoops. The tissue removal device may include one or more hoops, rings or any other flexible structure, including inflatable structures, or combinations thereof. All such changes and modifications are intended to be included within the scope of the disclosure.

15

20

IN THE CLAIMS

What is claimed is:

1. A tissue removal device, comprising:
a tubular body having a distal end, a proximal end and defining a lumen at least
5 partially therethrough;
a bag support structure configured and dimensioned to be receivable within the
lumen of the tubular body, wherein the bag support structure has a first configuration for
positioning within the lumen of the tubular body and a second configuration for opening a
bag operatively coupled thereto;
10 a bag operatively coupled to the bag support structure, the bag including a first end
portion defining an open end, a mid-portion, and a second end portion opposite the first
end portion; and
the bag support structure including a first member disposed between the first end
portion and the second end portion for at least partially closing the bag.
15
2. The tissue removal device of claim 1, wherein the first member comprises a
ring operatively connected to a distal end of a rod.
3. The tissue removal device according to any of the preceding claims,
20 wherein the first member comprises a first hoop operatively connected to the first end
portion of the bag and further comprises a second member comprising a second hoop
operatively connected to the bag at a location spaced a distance from the first end portion.
4. The tissue removal device as in any of the preceding claims, wherein each
25 of the first and second hoops has a first configuration in which the bag is substantially
closed and a second configuration in which the bag is substantially open.
5. The tissue removal device as in any of the preceding claims, wherein each
30 of the first and second hoops is made of a wire extending through at least one aperture
formed in the distal end of the shaft, wherein displacement of the wire of each of the first
and second hoops, in a distal direction, urges the respective one of the first and second
hoops to the second configuration, and wherein displacement of the wire of each of the
first and second hoops, in a proximal direction, urges the respective one of the first and
second hoops to the first configuration.

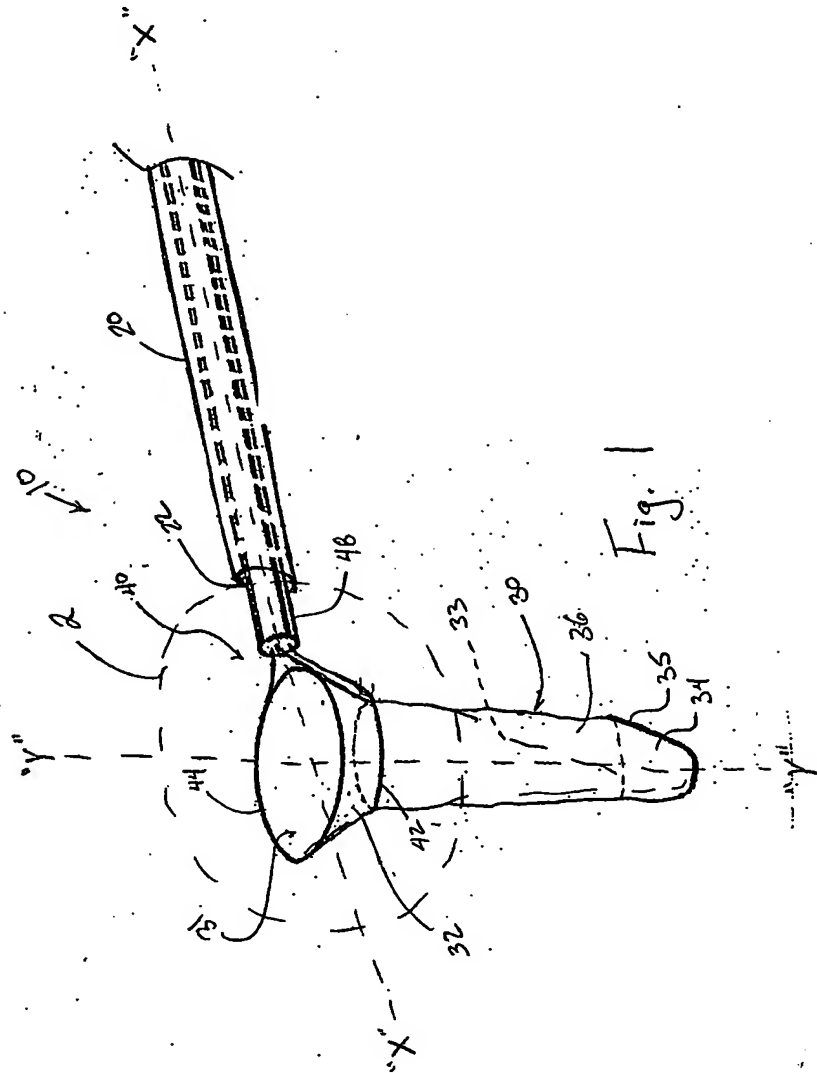
6. The tissue removal device according to any of the preceding claims,
wherein the ring is operatively connected to the first end portion of the bag, and wherein
the hoop is operatively connected to the bag at a location spaced a distance from the first
5 end portion of the bag.

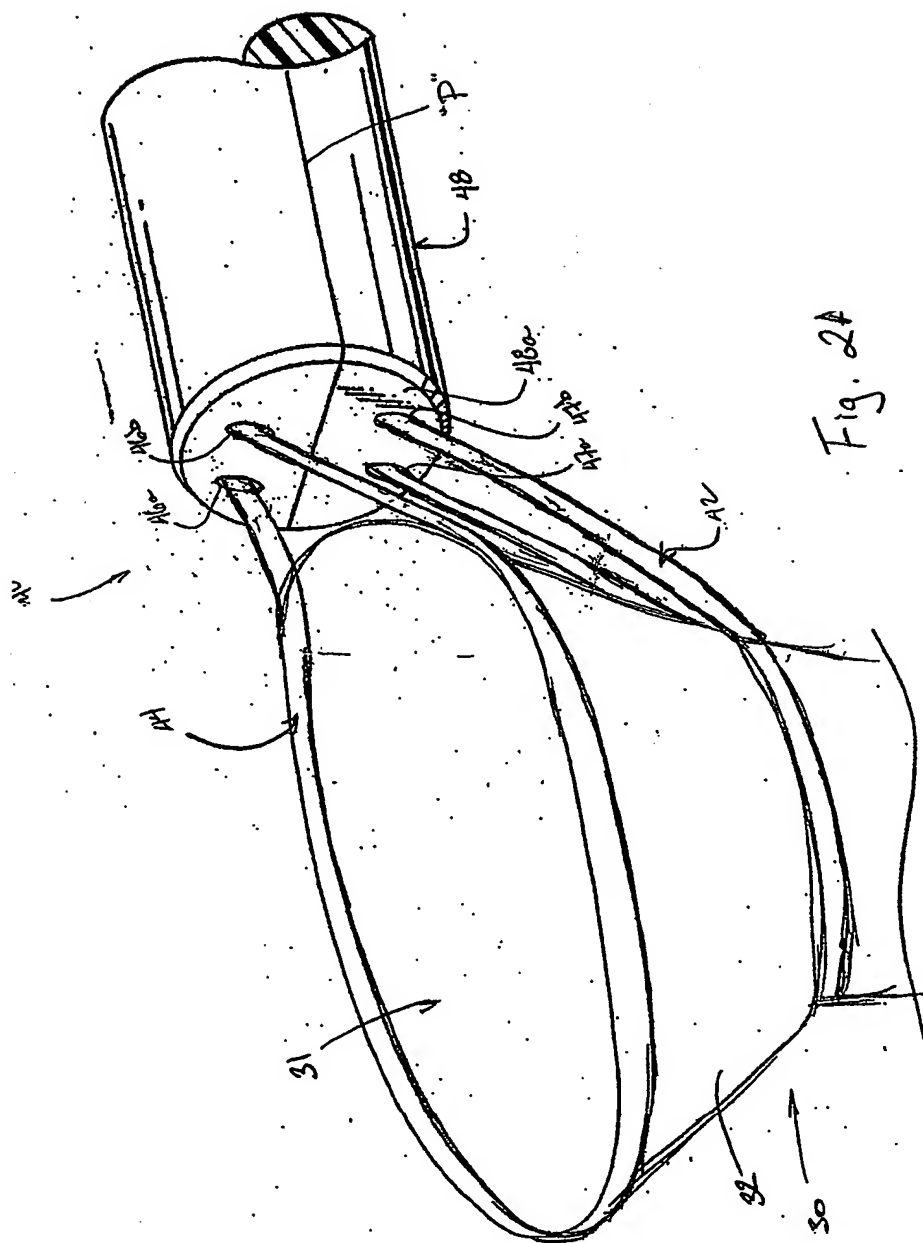
7. The tissue removal device according to any of the preceding claims,
wherein the ring is resilient, and wherein the ring has a first configuration in which the
ring is biased for receipt in the lumen of the tubular body and a second configuration in
10 which the ring is unbiased and has a diameter larger than the diameter of the lumen of the
tubular body.

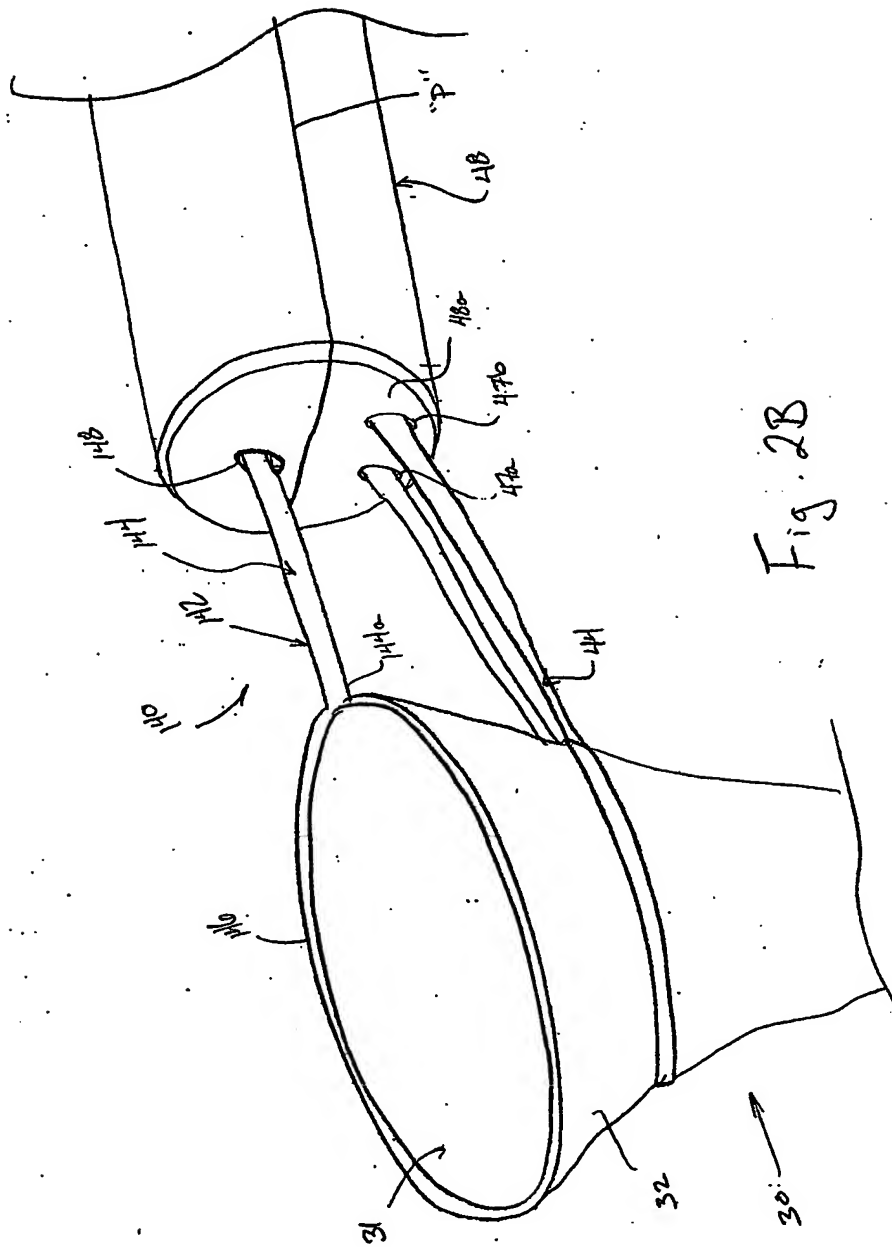
8. The tissue removal device according to any of the preceding claims,
wherein a mid-portion of the bag has a first diameter and wherein the first end portion of
15 the bag has a second diameter which is greater than the first diameter of the mid-portion.

9. The tissue removal device according to any of the preceding claims, further
comprising a removable sheath for encasing the bag and the distal end of the bag support
structure therein.
20

10. The tissue removal device according to any of the preceding claims, further
comprising a plurality of ribs extending longitudinally along a length of the bag.







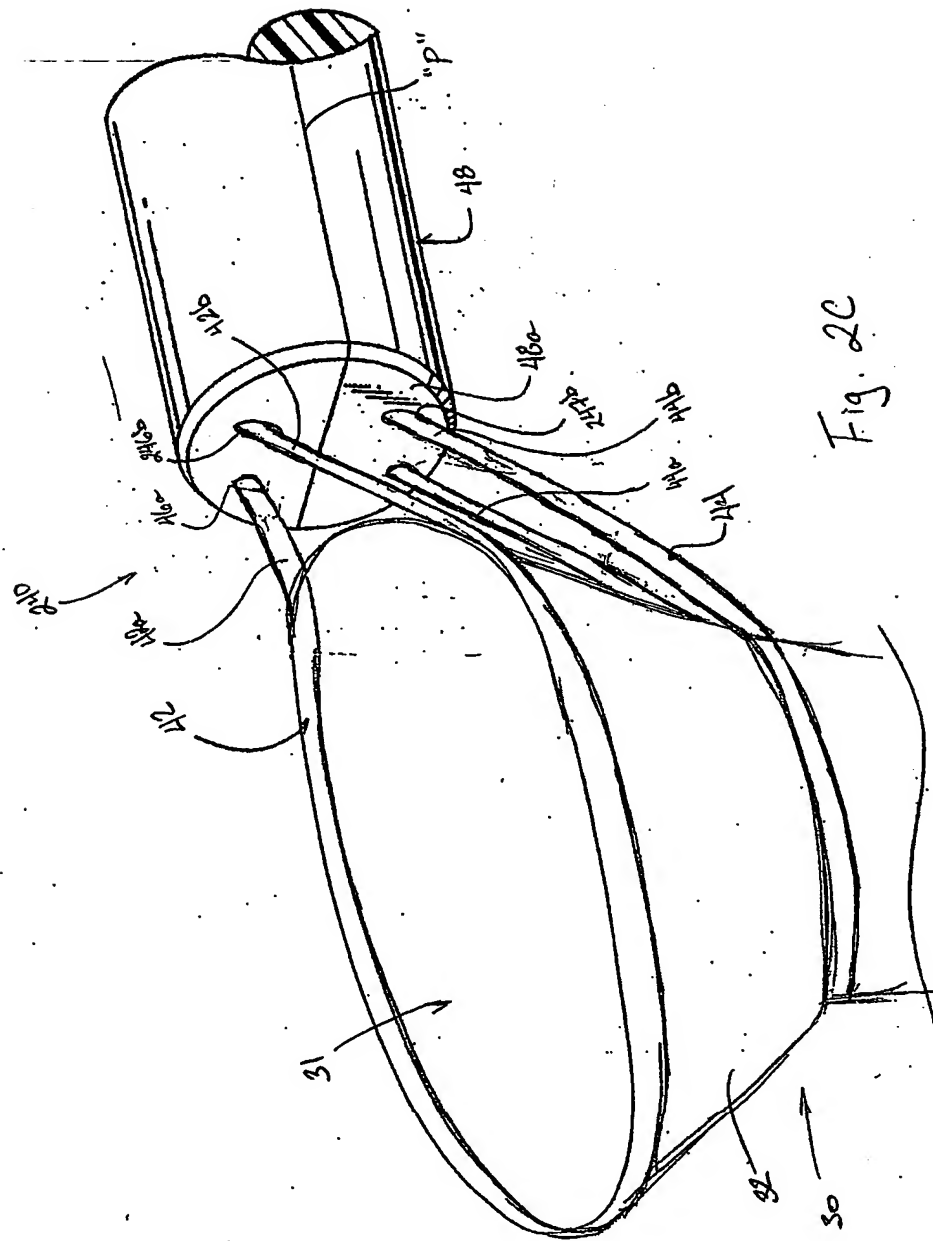


Fig. 2c

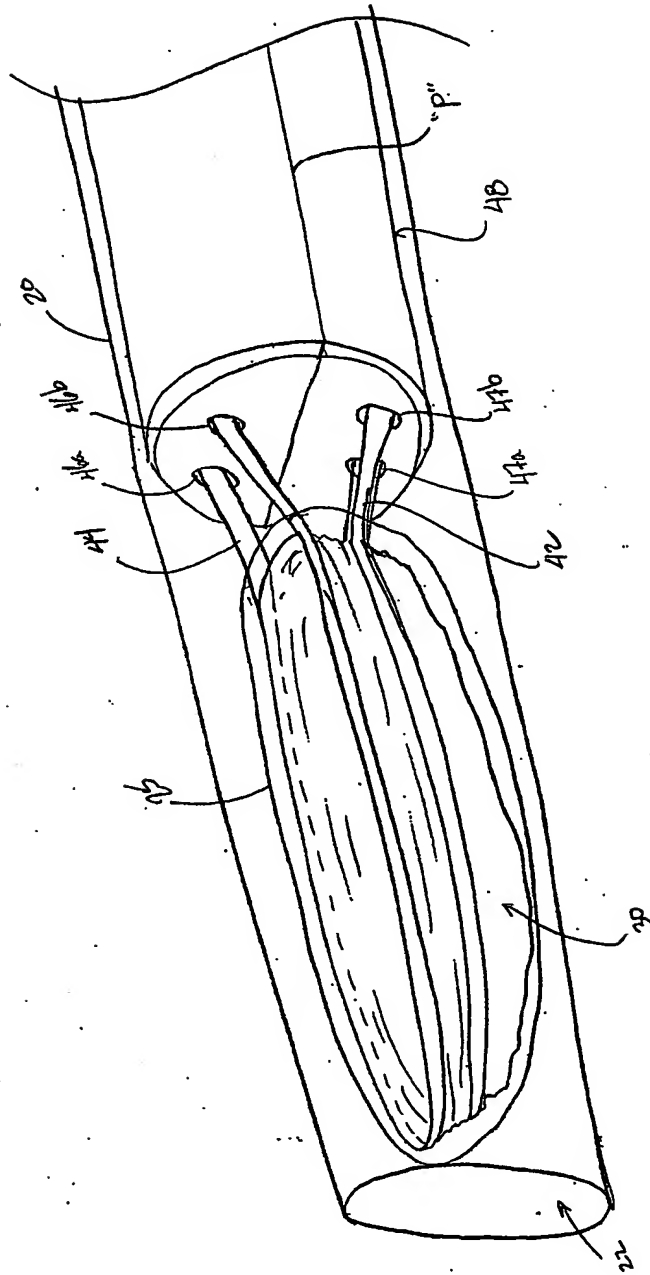


Fig. 3

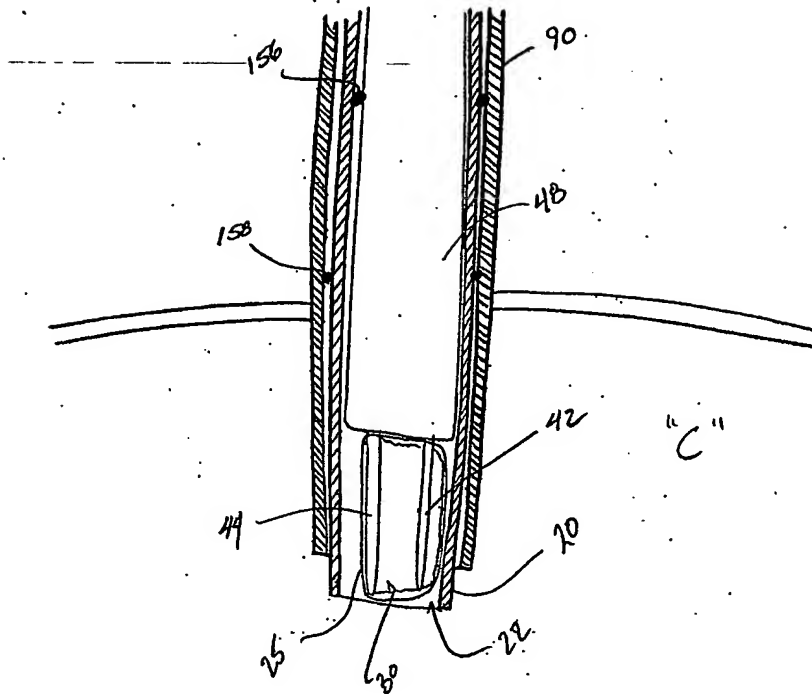
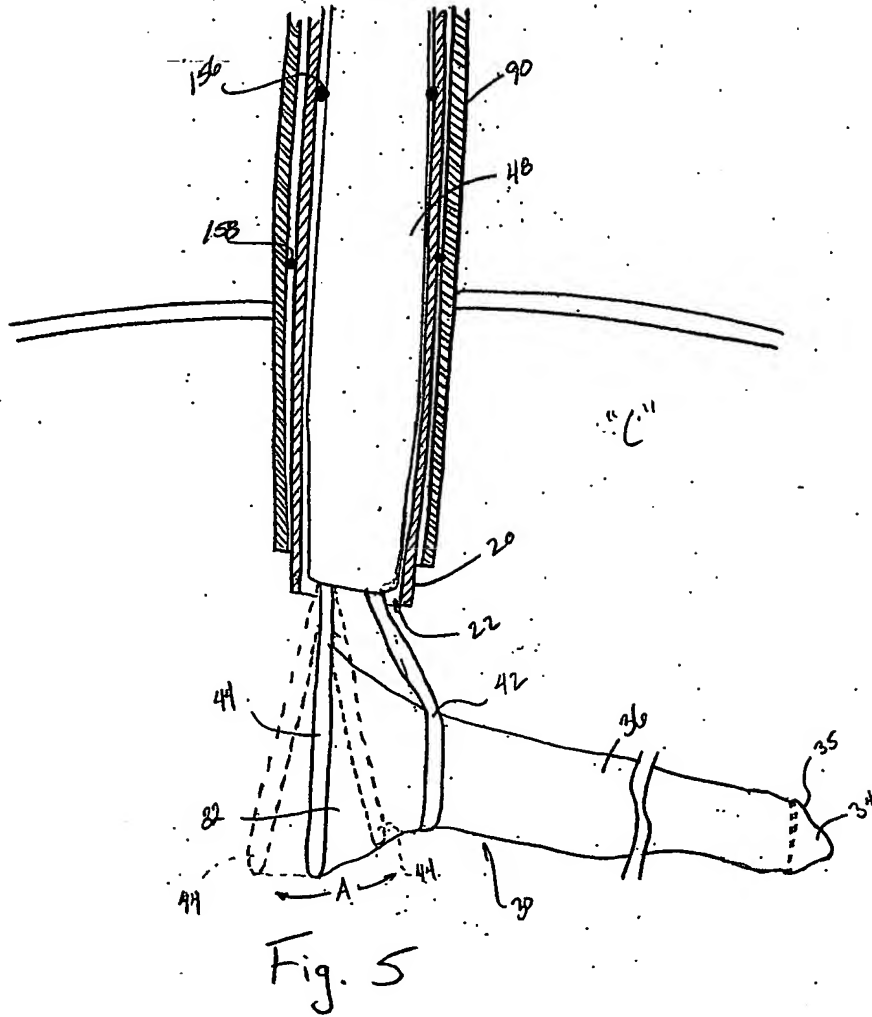


Fig. 4



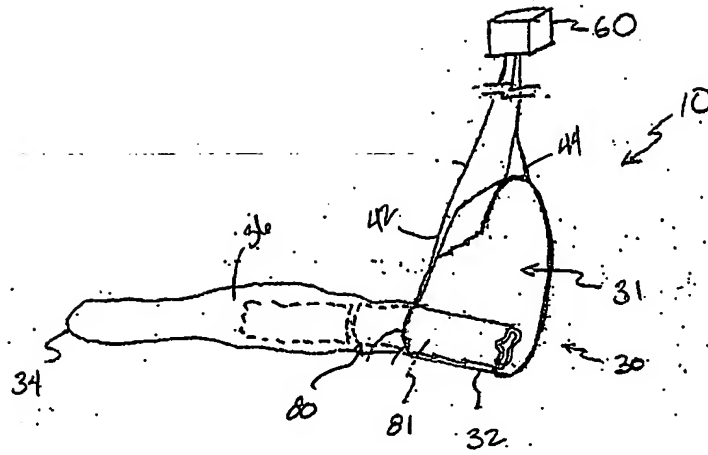


Fig. 6

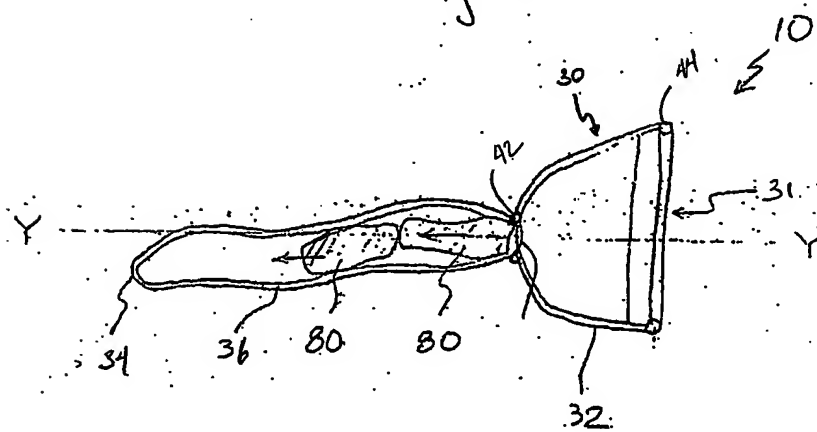


Fig. 7

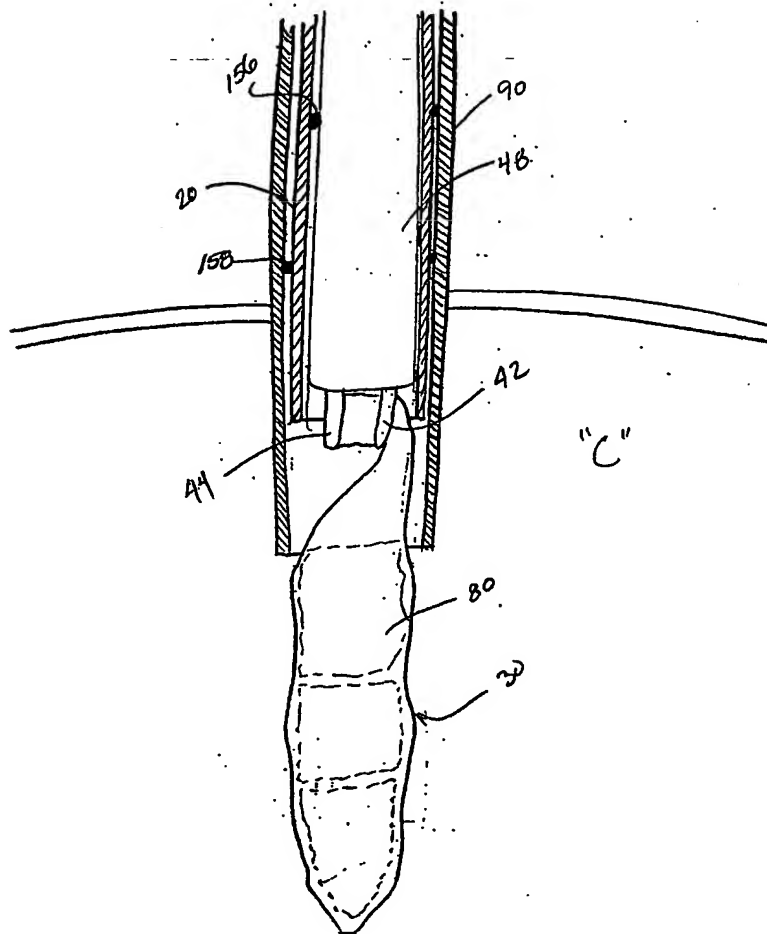


Fig. 8

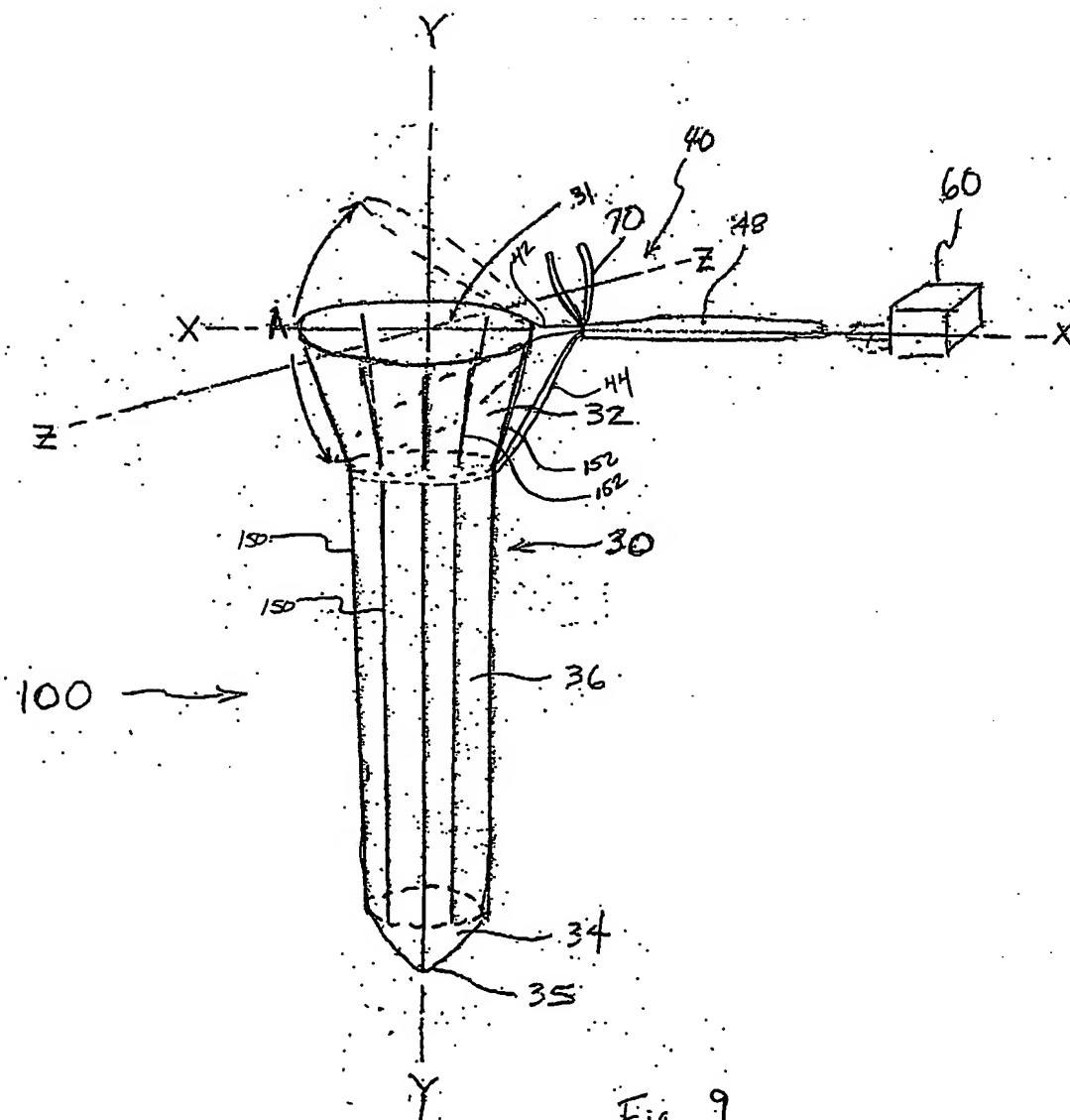


Fig. 9